REMARKS

The Examiner is thanked for indicating the withdrawal of the rejection under 35 U.S.C.§112, econd paragraph.

Claims 1-2, 4-5, 9-13, 16-20, 22-35, 39-43 and 46-61 were rejected under 35 U.S.C. §103(a) as being unpatentable over Timmins et al. (Timmins).

Reconsideration is requested.

The Timmins patent has been applied under 35 U.S.C.§103(a) which provides that a patent may not be obtained though the invention is not identically disclosed in the prior art if the the differences between the subject matter sought to be patented and the prior art are such that the subject matter "**as a whole**" would have been obvious to a person skilled in the art to which the subject pertains.

The language of the statute highlights the fact that claims that are rejected under 35 U.S.C.§103 define novel subject matter and do not extend their scope so that they embrace the tablets disclosed by the prior art, i.e., Timmins. For this reason, the scope and content of the Timmins patent and the differnces beteen the Timmins patent and the presently claimed invention must be considered in making a determination of patentability.Cf. *Graham v. John Deere*, 383 U.S.1; 148 USPQ 459 (1966)

The Timmins patent is limited to a biphasic controlled release delivery system for highly soluble drugs such as metformin hydrochloride, which is embodied in a dosage form that has a prolonged gastric residence time and that swells following hydration. The Timmins specification explicitly requires that the Timmins dosage formulation must swell as it operates by

increasing the time that the dosage remains in the stomach. The increase in the residence time of the Timmins tablet, in the stomach, is achieved by the use of polymers that swell on contact with water. (Cf. Timmins col. 20, lines 55-60). Thus in evaluating the scope and content of the Timmins teachings, one must acknowledge that if a tablet does not swell and it is novel over the teachings of Timmins, a real and substantial differnece actually exists between the claimed tablet and the Timmins disclosure.

When the teachings of Timmins are utilized to make a dosage form, a skilled person in the art would be directed to use at least one hydrophilic polymer in following the teachings of Timmins in making a sustained release formulation. Nothing in Timmins even remotely suggests a formulation which contains hydrophobic polymers as pointed out in claim 1 and the claims that are dependent on claim 1 of the present appliation. Hydrophobic polymers do not readilly absorb water and swell in the manner that the Timmins hydrophilic polymer must swell to provide the bulk that delays the exit of the Timmins tablet from the stomach when the Timmmins tablets are ingested. This fundamental difference between the Timmins tablet and the tablet defined by the claims of the present application, points to the unobviousness of the presently claimed invention.

Attached to this Amendment is a Declaration which reports the results of placing tablets made according to the present invention in pH 6.8 dissolution medium. The results show no appreciable swelling even after 12 hours of exposure to the dissolution media. This test demonstrates that the claimed tablets do not have an essential property of the Timmins tablets which is the property that Timmins disclosed as the operable basis of his tablets. This demonstration of the lack of a property in the claimed tablet, that is described as necessary

for the prior art tablet to be opoerative, while the tablet still is an opoerable tablet, is convincing e=vidence of non-obviousness.

In Timmins, the final size of the dosage form becomes very large due to the large quantity of polymer required and thus the Timmins approach to the making of a useful formulation of a drug that must be administered in high doses (i.e. 1000mg), such as metformin, is not practical due the difficulty the patient will have in swallowing a very large size dosage form. This problem is exacerbated in older patient populations who often take these medications. The instant invention, as pointed out in claim 1, is directed to a dosage form containing a high solubility active ingredient in a sustained release form. Thus, if Timmins approach of formulation is adopted the final dosage form will become very large and cannot be ingested by many if not all patients.

The following Table is derived from Timmins and it illustrates the high amounts of polymer relative to the active pharmaceutical ingredient (API) that result from the Timmins technique.

Example-1	500g API + 376.5g polymer	75% polymers by wt of API
Example-2	500g API + 391g polymer	78% polymers by wt of API
Example-3	500g API + 408 g polymer	81% polymers by wt of API
Example-4	500g API + >400 g polymer	81% polymers by wt of API

If we compare examples for the preparation of micromatrix particles of the same drug as shown in the present specification (e.g. Example 8-10 21-25% polymer), the final size of the dosage form will actually be much smaller as compared to the Timmins dosage form. This will make it possible to restrict the size of the dosage form of high solubility drug in sustained release form. This is clear from all the examples of the Timmins, which only contains 500mg of drugs, whereas with instant invention it has become possible to prepare dosage form of 1000mg of active, while keeping the size of final dosage form suitable for swallowing.

Thus, it is clear that, if the teachings of Timmins are applied, any person skilled in art would end up making a large sized dosage form for highly soluble drugs.

As mentioned above another common problem with a modified release dosage form of a highly soluble drug is dose dumping which is essentially a burst effect in-vivo.

Thus, Timmins et al does not teach such a technique for high solubility drugs, which reduces the burst effect and also reduces the size of the dosage form.

For these reasons, Timmins does not teach the claimed dosage form of the claims which is a swellable tablet for ***a, high solubility active ingredient***, as a modified release, which uses a reduced quantity of polymers to control the release of a high soluble drug while providing a compact dosage form suitable for swallowing.

Claims 24. 27-28 and 29 were rejected under 35 U.S.C. §103(a) as being unpatentable over Timmins in view of the Merck Index.

Timmins has been distinguished from the claimed invention above. As mentioned above any skilled artisan using the teachings of Timmins would end up having a large size dosage

form even with valproic acid or niacin which would have to swell to be operative. Drugs like valproic acid and niacin do not have an absorption window and hence the teachings from Timmins can not be applied to these drugs. Hence it is respectfully submitted that claims 24, 27-28, and 29 are not obvious under 35 U.S.C.§ 103(a) over Timmins and Merck Index.

An early and favorable action is earnestly solicited.

Respectfully submitted,

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